UNITED STATES DISTRICT COURT FOR THE DISTRICT OF VERMONT

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UNITED STATES OF AMERICA,
                                         )
     Plaintiff,
                                         Civ. No. 06-
             V.
THE STATE OF VERMONT; THE
HONORABLE JAMES H. DOUGLAS,
                                         )
Governor of the State of Vermont, )
in his official capacity only;
CYNTHIA D. LaWARE, Secretary, )
Vermont Agency of Human Services, )
in her official capacity only;
PAUL E. JARRIS, Commissioner,
Vermont Department of Health, in
                                  )
his official capacity only;
PAUL R. BLAKE, Deputy
Commissioner, Vermont Division of )
Mental Health, in his official)
capacity only; and TERRY ROWE, )
Executive Director, Vermont State )
Hospital, in her official capacity)
only,
      Defendants.
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SETTLEMENT AGREEMENT

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I. GENERAL PROVISIONS

- B. This Settlement Agreement (the "Agreement") is entered into between the United States and the State of Vermont; the Vermont Agency of Human Services; the Vermont Department of Health; the Vermont Division of Mental Health; and the Vermont State Hospital (collectively referred to as "the State").
- C. The Agreement resolves the investigation conducted by the United States Department of Justice ("United States") at the Vermont State Hospital ("VSH") pursuant to the Civil Rights of Institutionalized Persons Act ("CRIPA"), 42 U.S.C. § 1997. The Agreement addresses the corrective measures set forth by the United States in its letter to the State dated July 5, 2005 ("Findings Letter"). This Agreement does not serve as an admission by the State that corrective measures are necessary to meet the constitutional and statutory rights of the residents of VSH.
- D. In conformity with CRIPA, this Agreement represents a voluntary effort by the State to meet the concerns raised by the United States' investigation. See 42 U.S.C. § 1997b (a)(2)(B) and § 1997g.
- E. Pursuant to 42 U.S.C. § 1997b(a)(2)(B) and § 1997g, the United States agrees to support the State's application for federal funding conditioned upon the State's proper implementation of the suggested remedial measures.
- F. Nothing in this Agreement shall be construed as an acknowledgment, an admission, or evidence of liability of the State under CRIPA, the Constitution or federal or state law, and this Agreement may not be used as evidence of liability in this or any other civil or criminal proceeding.
- G. The signatures below of officials representing the United States and the State signify that these parties have given their final approval to this Agreement.
- H. This Agreement is enforceable only by the parties or the Court. This Agreement is binding upon the parties, by and through their officials, agents, employees, and successors. No person or entity is intended to be a third party beneficiary of the provisions of this Agreement for purposes of any civil, criminal, or administrative action, and, accordingly, no person or entity may assert any claim or right as a beneficiary or protected class under this Agreement in any civil, criminal, or administrative action. Similarly, this Agreement does not authorize, nor shall it be construed to authorize, access to State documents by persons or entities not a party to this Agreement.
- I. This Agreement shall constitute the entire integrated Agreement of the parties.

 No prior contemporaneous communications, oral or written, or prior drafts shall be relevant or admissible for purposes of determining the meaning of any

provisions herein in any litigation or any other proceeding. Any amendment to this Agreement shall be in writing, signed by both parties, as provided under Section XIV.M.

- J. Since the United States issued the July 5, 2005 Findings Letter, the State has made progress in remedying the problems the United States identified in the Findings Letter. The parties agree that it is in their mutual interests to avoid litigation. The parties further agree that resolution of this matter pursuant to this Agreement is in the best interests of VSH residents. Now, therefore, pursuant to Fed. R. Civ. P. 41(a)(2), the parties hereby agree to file in the United States District Court for the District of Vermont this Agreement, together with a Complaint and a motion to conditionally dismiss the Complaint under the conditions set forth in this Agreement. The parties further agree that this case will remain on the Court's inactive docket, during the term of, and subject to, this Agreement, and that, from time to time, the Court may hold, at the request of either party, status conferences to informally resolve disputes between the parties, if any, until this Agreement terminates.
- K. All parties shall bear their own costs, including attorneys' fees, in this and any subsequent proceeding.
- L. This Agreement shall take effect on the day it is filed with the United States District Court for the District of Vermont.

II. **DEFINITIONS**

A. Effective Date

The Effective Date hereof shall be the date that it is filed. Unless otherwise specified, each provision of this Agreement shall be implemented by 30 months from the Effective Date hereof

B. Consistent With Generally Accepted Professional Standards of Care

A decision by a qualified professional that is not such a substantial departure from contemporary, accepted professional judgment, practice, or standards as to demonstrate that the person responsible did not base the decision on such accepted professional judgment.

C. Incident

As required under Section XI of this Agreement, VSH will identify categories and definitions of incidents to be reported and investigated, and such categories and definitions shall include, but not be limited to, death, abuse, neglect, and serious injury.

III. INTRODUCTION

- A. Care and treatment provided by VSH shall be based on professional standards of practice and shall be designed to:
 - 1. ameliorate symptoms such that a less restrictive locus of treatment may safely be employed;
 - 2. strengthen and support individuals' rehabilitation and recovery; and
 - 3. enable individuals to grow and develop in ways benefitting their health and well-being.
- B. This shall be accomplished while maximizing individuals' safety, security, and freedom from undue bodily restraint. Relationships between VSH staff and individuals whom they serve shall be therapeutic and respectful.
- C. Each individual served by VSH shall be encouraged to participate in identifying his or her treatment goals and in selecting appropriate treatment options. Care and treatment shall be designed to address each individual's psychiatric treatment needs and to assist individuals in meeting their specific treatment goals, consistent

with generally accepted professional standards of care. VSH shall ensure clinical and administrative oversight of, education of, and support to, its staff in planning and providing care and treatment consistent with these standards.

IV. INTEGRATED TREATMENT PLANNING

By 30 months from the Effective Date hereof, VSH shall provide integrated, individualized protections, services, supports, and treatments (collectively "treatment") for the individuals it serves, consistent with generally accepted professional standards of care. In addition to implementing the discipline-specific treatment planning provisions set forth below, VSH shall establish and implement standards, policies, and protocols and/or practices to provide that treatment determinations are consistently coordinated by an interdisciplinary team through integrated treatment planning and embodied in a single, integrated plan.

B. Interdisciplinary Teams

By 30 months from the Effective Date hereof, each interdisciplinary team's membership shall be dictated by the particular needs, strengths, and preferences of the individual in the team's care, and, at a minimum, the interdisciplinary team for each individual shall:

- 1. have as its primary objective the provision of individualized, integrated treatment that optimizes the patient's opportunity for recovery and ability to sustain himself/herself in the most appropriate, least restrictive setting, and supports the patient's interests of self determination and independence;
- 2. be led by a treating psychiatrist who, at a minimum, shall:
 - a. assume primary responsibility for the individual's treatment;
 - b. require that each member of the team participates appropriately in assessing the individual on an ongoing basis and in developing, monitoring, and, as necessary, revising treatments;
 - c. require that the treatment team functions in an interdisciplinary fashion; and
 - d. require that the scheduling and coordination of assessments and team meetings, the drafting of integrated treatment plans, and the scheduling and coordination of necessary progress reviews occur in a timely fashion;

- 3. have its composition dictated by the individual's particular needs, strengths, and preferences, but shall consist of a stable core of members, including the individual, the treating psychiatrist, the nurse, and the social worker and, as the core team determines is clinically appropriate, other team members, who may include the individual's family, guardian, advocates, and the pharmacist and other clinical staff;
- 4. complete training on the development and implementation of interdisciplinary treatment plans to the point that integrated treatment plans meet the requirements of section IV.B., infra; and
- 5. meet every 30 days, and more frequently as clinically indicated.

B. Integrated Treatment Plans

By 24 months from the Effective Date hereof, VSH shall develop and implement policies and/or protocols regarding the development of treatment plans consistent with generally accepted professional standards of care, to provide that:

- 1. where possible, individuals have substantive, identifiable input into their treatment plans;
- 2. treatment planning provides timely attention to the needs of each individual, in particular:
 - a. initial treatment plans are completed within 24 hours of admission;
 - b. master treatment plans are completed within seven days of admission; and
 - treatment plan reviews are performed every
 14 days during the first 60 days of hospitalization and every 30 days thereafter;
- 3. individuals are informed of the purposes and side effects of medication;
- 4. each treatment plan specifically identifies the therapeutic means by which the treatment goals for the particular individual shall be addressed, monitored, reported, and documented, consistent with generally accepted professional standards of care; and
- 5. treatment and medication regimens are modified, as appropriate, considering factors such as the individual's response to treatment, significant developments in the individual's condition, and the individual's changing needs.

- C. By 30 months from the Effective Date hereof, VSH shall use these policies and/or protocols to provide that treatment planning is based on a comprehensive case formulation for each individual that emanates from an integration of the discipline-specific assessments of the individual consistent with generally accepted professional standards of care. Specifically, the case formulation shall:
 - 1. be derived from analyses of the information gathered from discipline-specific assessments, including diagnosis and differential diagnosis;
 - 2. include a review of pertinent history, predisposing, precipitating, and perpetuating factors, present status, and previous treatment history;
 - 3. consider biochemical and psychosocial factors for each category in Section IV.C.2., supra;
 - 4. consider such factors as age, gender, culture, treatment adherence, and medication issues that may affect the outcomes of treatment interventions;
 - 5. enable the treatment team to reach sound determinations about each individual's treatment and habilitation needs; and
 - 6. make preliminary determinations as to the least restrictive setting to which the individual should be discharged, and the changes that will be necessary to achieve discharge.
- D. By 30 months from the Effective Date hereof, VSH shall use these policies and/or protocols to provide that treatment planning is driven by individualized needs, is strengths-based (i.e., builds on an individual's current strengths), and that it provides an opportunity to improve each individual's health and well being, consistent with generally accepted professional standards of care. Specifically, the treatment team shall:
 - develop and prioritize reasonable and attainable goals/objectives (i.e., relevant to each individual's level of functioning) that build on the individual's strengths and address the individual's identified needs and, if any identified needs are not to be addressed, provide a rationale for not addressing the need;
 - 2. provide that the goals/objectives address treatment (e.g., for a disease or disorder) and rehabilitation (e.g., skills/supports/quality of life activities);
 - 3. write the objectives in behavioral and measurable terms;

- 4. provide that there are interventions that relate to each objective, specifying who will do what and within what time frame, to assist the individual to meet his/her goals as specified in the objective;
- 5. design a program of interventions throughout the individual's day with a minimum of 20 hours of clinically appropriate treatment/rehabilitation per week; and
- 6. provide that each treatment plan integrates and coordinates all selected services, supports, and treatments provided by or through VSH for the individual in a manner specifically responsive to the plan's treatment and rehabilitative goals.
- E. By 30 months from the Effective Date hereof, VSH shall revise treatment plans, as appropriate, to provide that planning is outcome-driven and based on the individual's progress, or lack thereof, as determined by the scheduled monitoring of identified treatment objectives, consistent with generally accepted professional standards of care. Specifically, the treatment team shall:
 - 1. revise the objectives, as appropriate, to reflect the individual's changing needs;
 - 2. monitor, at least monthly, the goals, objectives, and interventions identified in the plan for effectiveness in producing the desired outcomes;
 - 3. review the goals, objectives, and interventions more frequently than monthly if there are clinically relevant changes in the individual's functional status or risk factors;
 - 4. provide that the review process includes an assessment of progress related to discharge; and
 - 5. base progress reviews and revision recommendations on data collected as specified in the treatment plan.

V. MENTAL HEALTH ASSESSMENTS

By 24 months from the Effective Date hereof, VSH shall ensure that, consistent with generally accepted professional standards of care, each individual shall receive, promptly after admission to VSH, an assessment of the conditions responsible for the individual's admission, and provide that it is accurate and complete to the degree possible given the obtainable information at the time of admission. To the degree possible given the obtainable information, the individual's interdisciplinary team shall be responsible for investigating the past and present

medical, nursing, psychiatric, and psychosocial factors bearing on the patient's condition, and, when necessary, for revising assessments and treatment plans in accordance with new information that comes to light. Thereafter, each individual shall receive a reassessment whenever there has been a significant change in the individual's status, a lack of expected improvement resulting from treatment clinically indicated, or six months since the previous reassessment.

A. Psychiatric Assessments and Diagnoses

- 1. By 24 months from the Effective Date hereof, VSH shall use the diagnostic protocols in the most current Diagnostics and Statistics Manual ("DSM") for reaching the most accurate psychiatric diagnoses.
- 2. By 24 months from the Effective Date hereof, VSH shall ensure that all psychiatric assessments are consistent with VSH's standard diagnostic protocols.
- 3. By 24 months from the Effective Date hereof, VSH shall ensure that, within 24 hours of an individual's admission to VSH, the individual receives an initial psychiatric assessment, consistent with VSH's protocols.
- 4. By 24 months from the Effective Date hereof, VSH shall ensure that:
 - a. clinically justifiable, current assessments and diagnoses are provided for each individual;
 - b. the documented justification of the diagnoses are in accord with the criteria contained in the most current DSM;
 - c. differential diagnoses, "rule-out" diagnoses, and diagnoses listed as "NOS" ("Not Otherwise Specified") are timely addressed, through clinically appropriate assessments, and resolved in a clinically justifiable manner; and
 - d. each individual's psychiatric assessments, diagnoses, and medications are clinically justified consistent with generally accepted professional standards of care.
- 5. By 18 months from the Effective Date hereof, VSH shall develop protocols consistent with generally accepted professional standards of care to ensure an ongoing and timely reassessment of the psychiatric causes of the individual's continued hospitalization.

A. Psychological Assessments

- 1. By 30 months from the Effective Date hereof, VSH shall ensure that patients referred by the treating psychiatrist for psychological assessment receive that assessment, consistent with generally accepted professional standards of care, in a timely manner. These assessments may include diagnostic neuropsychological assessments, cognitive assessments, and I.Q./achievement assessments to guide psychoeducational (e.g., instruction regarding the illness or disorder, and the purpose or objectives of treatments for the same, including medications), rehabilitation and habilitation interventions, behavioral assessments (including functional analysis of behavior in all settings), and personality assessments.
- 2. By 30 months from the Effective Date hereof, all psychological assessments, consistent with generally accepted professional standards of care, shall:
 - a. expressly state the purpose(s) for which they are performed;
 - b. be based on current, accurate, and complete data;
 - c. include an accurate, complete, and up-to-date summary of the individual's relevant, clinical, and functional history and response to previous treatment;
 - d. where relevant to the consultation, include sufficient elements of behavioral assessments to determine whether behavioral supports or interventions are warranted or whether a comprehensive applied behavioral analysis and plan are required;
 - e. include determinations specifically addressing the purpose(s) of the assessment;
 - f. include a summary of the empirical basis for all conclusions, where possible; and
 - g. identify any unresolved issues encompassed by the assessment and, where appropriate, specify further observations, records, or re-evaluations that should be undertaken in endeavoring to resolve such issues.
- 3. By 30 months from the Effective Date hereof, previously completed psychological assessments of individuals currently at VSH shall be reviewed by qualified clinicians and, as indicated, revised to meet the criteria in Section V.B., supra. By 30 months from the Effective Date

hereof, appropriate psychological assessments shall be provided in a timely manner, whenever clinically determined by the team, consistent with generally accepted professional standards of care. These may include whenever there has been a significant change in condition, a lack of expected improvement resulting from treatment, or an individual's behavior poses a significant barrier to treatment or therapeutic programming. The assessment may also be used where clinical information is otherwise insufficient and to address unresolved clinical or diagnostic questions, including "rule-out" and deferred diagnoses.

4. By 30 months from the Effective Date hereof, when an assessment is completed, VSH shall ensure that treating psychologists communicate and interpret psychological assessment results to the treatment teams, along with the implications of those results for diagnosis and treatment.

B. Rehabilitation Assessments

- 1. The treating psychiatrist shall determine and document his or her decision, prior to the initial treatment team meeting, whether a comprehensive rehabilitation assessment is required for a patient. When requested by the treating psychiatrist, or otherwise requested by the treatment team or member of the treatment team, VSH shall perform a comprehensive rehabilitation assessment, consistent with generally accepted professional standards of care and the requirements of this Agreement. Any decision not to require a rehabilitation assessment shall be documented in the patient's record and contain a brief description of the reason(s) for the decision.
- 2. By 30 months from the Effective Date hereof, all rehabilitation assessments will be consistent with generally accepted professional standards of care and shall:
 - a. be accurate and coherent as to the individual's functional abilities;
 - b. identify the individual's life skills prior to, and over the course of, the mental illness or disorder;
 - c. identify the individual's observed and, separately, expressed interests, activities, and functional strengths and weaknesses; and
 - d. provide specific strategies to engage the individual in appropriate activities that he or she views as personally meaningful and productive.

3. By 30 months from the Effective Date hereof, rehabilitation assessments of all individuals currently residing at VSH who were admitted there before the Effective Date hereof shall be reviewed by qualified clinicians and, as indicated, revised to meet the criteria in Section V.C.2., supra.

D. Social History Assessments

By 18 months from the Effective Date hereof, VSH shall ensure that each individual has a social history evaluation that is consistent with generally accepted professional standards of care. This includes identifying factual inconsistencies among sources, resolving or attempting to resolve inconsistencies, explaining the rationale for the resolution offered, and reliably informing the individual's treatment team about the individual's relevant social factors.

VI. DISCHARGE PLANNING AND COMMUNITY INTEGRATION

Taking into account the limitations of court-imposed confinement, VSH shall pursue actively the appropriate discharge of individuals to the most integrated, appropriate setting that is consistent with each person's needs and to which they can be reasonably accommodated, taking into account the resources available to the State and the needs of others with mental disabilities.

- E. By 30 months from the Effective Date hereof, VSH shall identify at admission and address in treatment planning the particular considerations for each individual bearing on discharge, including:
 - 1. those factors that likely would foster successful discharge, including the individual's strengths, preferences, and personal goals;
 - 2. the individual's symptoms of mental illness or psychiatric distress;
 - 3. barriers preventing the specific individual from being discharged to a more integrated environment, especially difficulties raised in previously unsuccessful placements, to the extent that they are known; and
 - 4. the skills necessary to live in a setting in which the individual may be placed.
- B. By six months from the Effective Date hereof, VSH shall provide the opportunity, beginning at the time of admission and continuously throughout the individual's stay, for the individual to be an active participant in the discharge planning process, as appropriate.

- C. By 30 months from the Effective Date hereof, VSH shall ensure that, consistent with generally accepted professional standards of care, each individual has a discharge plan that is a fundamental component of the individual's treatment plan and that includes:
 - 1. measurable interventions regarding his or her particular discharge considerations;
 - 2. the persons responsible for accomplishing the interventions; and
 - 3. the time frames for completion of the interventions.
- D. By 24 months from the Effective Date hereof, when clinically indicated, VSH shall transition individuals into the community consistent with generally accepted professional standards of care. In particular, VSH shall ensure that individuals receive adequate assistance in transitioning prior to discharge.
- E. Discharge planning shall not be concluded without the referral of a resident to an appropriate set of supports and services, the conveyance of information necessary for discharge, the acceptance of the resident for the services, and the discharge of the resident.
- F. By 30 months from the Effective Date hereof, the State shall develop and implement a quality assurance/improvement system to monitor the discharge process.

VII. SPECIFIC TREATMENT SERVICES

A. Psychiatric Care

By 30 months from the Effective Date hereof, VSH shall provide all of the individuals it serves with adequate and appropriate routine and emergency psychiatric and mental health services consistent with generally accepted professional standards of care.

- 1. By 30 months from the Effective Date hereof, VSH shall develop and implement policies and/or protocols regarding the provision of psychiatric care consistent with generally accepted professional standards of care. In particular, policies and/or protocols shall address physician practices regarding:
 - a. documentation of psychiatric assessments and ongoing reassessments as per Section V.A., supra;

- b. documentation of significant developments in the individual's clinical status and of appropriate psychiatric follow up;
- c. timely and justifiable updates of diagnosis and treatment, as clinically appropriate;
- d. documentation of analyses of risks and benefits of chosen treatment interventions;
- e. assessment of, and attention to, high-risk behaviors (e.g., assaults, self-harm, falls) including appropriate and timely monitoring of individuals and interventions to reduce risks;
- f. documentation of, and responses to, side effects of prescribed medications; and
- g. timely review of the use of "pro re nata" or "as-needed" ("PRN") medications and adjustment of regular treatment, as indicated, based on such use.
- 2. By 30 months from the Effective Date hereof, VSH shall develop and implement policies and/or protocols to ensure system-wide monitoring of the safety, effectiveness, and appropriateness of all psychotropic medication use, consistent with generally accepted professional standards of care. In particular, policies and/or protocols shall address:
 - 1. monitoring of the use of psychotropic medications to ensure that they are:
 - i. clinically justified;
 - ii. prescribed in therapeutic amounts, as dictated by the needs of the individual patient;
 - iii. tailored to each individual's clinical needs;
 - iv. monitored for effectiveness against the objectives of the individual's treatment plan;
 - v. monitored appropriately for side effects; and
 - vi. properly documented;
 - b. monitoring of the use of PRN medications to ensure that these medications are clinically justified and administered on a time-limited basis:

- c. timely identification, reporting, data analyses, and follow up remedial action regarding adverse drug reactions reporting ("ADR");
- d. drug utilization evaluation ("DUE") in accord with established, up-to-date medication guidelines;
- e. documentation, reporting, data analyses, and follow up remedial action regarding actual and potential medication variances ("MVR");
- f. tracking of individual and group practitioner trends;
- g. feedback to the practitioner and educational/corrective actions in response to identified trends, when indicated; and
- h. use of information derived from ADRs, DUE, MVR, and providing such information to the Pharmacy & Therapeutics, Therapeutics Review, and Mortality and Morbidity Committees.
- 3. By 30 months from the Effective Date hereof, VSH shall ensure that all physicians and clinicians are performing in a manner consistent with generally accepted professional standards of care, to include appropriate medication management, treatment team functioning, and the integration of behavioral and pharmacological treatments.
- 4. By 30 months from the Effective Date hereof, VSH shall review and ensure the appropriateness of the medication treatment, consistent with generally accepted professional standards of care.
- 5. By 30 months from the Effective Date hereof, VSH shall ensure that individuals are screened and evaluated for substance abuse. For those individuals identified with a substance abuse disorder, VSH shall provide them with appropriate inpatient services consistent with their need for treatment.

B. Psychological Care

By 30 months from the Effective Date hereof, VSH shall provide adequate and appropriate psychological supports and services, consistent with generally accepted professional standards of care, to individuals who require such services.

1. By 30 months from the Effective Date hereof, VSH shall ensure, consistent with generally accepted professional standards of care, adequate

capacity to meet the needs of patients in the following areas of psychological services:

- a. behavioral treatment;
- b. group therapy;
- c. psychological testing;
- d. family therapy; and
- e. individual therapy.
- 2. By 30 months from the Effective Date hereof, VSH shall provide adequate clinical oversight to therapy groups to ensure that individuals are assigned to groups that are appropriate to their individual needs, that groups are provided consistently and with appropriate frequency, and that issues particularly relevant for this population, including the use of psychotropic medications and substance abuse, are appropriately addressed consistent with generally accepted professional standards of care.
- 3. By 30 months from the Effective Date hereof, VSH shall provide adequate active psychosocial rehabilitation, consistent with generally accepted professional standards of care, that:
 - a. is based on individualized assessment of patients' needs and is directed toward increasing patient ability to engage in more independent life functions;
 - b. addresses those needs in a manner building on the individual's strengths, preferences, and interests;
 - c. focuses on the individual's vulnerabilities to mental illness, substance abuse, and readmission due to relapse, where appropriate;
 - d. is provided in a manner consistent with each individual's cognitive strengths and limitations;
 - e. is provided in a manner that is clinically appropriate as determined by the treatment team;
 - f. routinely takes place as scheduled, for those interventions that are scheduled;

- g. includes, in the evenings and weekends, additional activities that enhance the individual's quality of life;
- h. prescribes a role for the staff on the living units; and
- i. is documented in the individual's treatment plan.
- 4. By 30 months from the Effective Date hereof, VSH shall ensure that:
 - a. behavioral interventions are based on positive reinforcements rather than the use of aversive contingencies, to the extent possible;
 - b. programs are consistent for each patient within all settings at VSH;
 - c. triggers for considering instituting individualized behavior treatment support plans are specified and utilized, and that these triggers include excessive use of seclusion, restraint, and emergency involuntary medication;
 - d. psychotherapy, whenever prescribed, is goal-directed, individualized, and informed by a knowledge of the individual's psychiatric, medical, and psychosocial history and previous response to psychotherapy;
 - e. psychosocial, rehabilitative, and behavioral interventions are monitored and revised as appropriate in light of significant developments, and the individual's progress, or the lack thereof;
 - f. clinically relevant information remains readily accessible; and
 - g. all staff who have a role in implementing individual behavioral programs have received competency-based training on implementing the specific behavioral programs for which they are responsible, and quality assurance measures are in place for monitoring behavioral treatment interventions.

C. Pharmacy Services

By 30 months from the Effective Date hereof, VSH shall provide adequate and appropriate pharmacy services consistent with generally accepted professional standards of care. By 30 months from the Effective Date hereof, VSH shall develop and implement policies and/or protocols that require:

- 1. pharmacists to complete reviews of each individual's medication regimen regularly, on at least a monthly basis, and, as appropriate, make recommendations to treatment teams about possible drug-to-drug interactions, side effects, medication changes, and needs for laboratory work and testing; and
- 2. physicians to consider pharmacists' recommendations, clearly document their responses and actions taken and, for any recommendations not followed, provide an adequate clinical justification.

VIII. DOCUMENTATION

By 30 months from the Effective Date hereof, VSH shall ensure that an individual's records accurately reflect the individual's progress as to all treatment identified in the individual's treatment plan, consistent with generally accepted professional standards of care. By 30 months from the Effective Date hereof, VSH shall develop and implement policies and/or protocols setting forth clear standards regarding the content and timeliness of progress notes, transfer notes, and discharge notes, including, but not limited to, an expectation that such records include meaningful, accurate assessments of the individual's progress relating to treatment plans and treatment goals.

IX. RESTRAINTS, SECLUSION, AND EMERGENCY INVOLUNTARY PSYCHOTROPIC MEDICATIONS

By 24 months from the Effective Date hereof, VSH shall ensure that restraints, seclusion, and emergency involuntary psychotropic medications are used consistent with generally accepted professional standards of care.

- A. By 18 months from the Effective Date hereof, VSH shall revise, as appropriate, and implement policies and/or protocols regarding the use of seclusion, restraints, and emergency involuntary psychotropic medications consistent with generally accepted professional standards of care. In particular, the policies and/or protocols shall expressly prohibit the use of mechanical restraints in a prone position and shall list the types of restraints that are acceptable for use.
- B. By 18 months from the Effective Date hereof, and absent exigent circumstances (i.e., when a patient poses an imminent risk of injury to himself or others), VSH shall ensure that restraints and seclusion:
 - 1. are used in a reliably documented manner and after a hierarchy of less restrictive measures has been considered in a clinically justifiable manner or exhausted;

- 2. are not used in the absence of, or as an alternative to, active treatment, as punishment, or for the convenience of staff;
- 3. are not used as part of a behavioral intervention; and
- 4. are terminated as soon as the individual is no longer an imminent danger to himself/herself or others, unless otherwise clinically indicated.
- C. By six months from the Effective Date hereof, VSH shall comply with 42 C.F.R. § 483.360(f), requiring assessments by a physician or licensed medical professional of any individual placed in seclusion or restraints. VSH shall also ensure that any individual placed in seclusion or restraints is continuously monitored by a staff person who has successfully completed competency-based training on the monitoring of seclusion and restraints.
- D. By 18 months from the Effective Date hereof, VSH shall ensure the accuracy of data regarding the use of restraints, seclusion, or emergency involuntary psychotropic medications.
- E. By 24 months from the Effective Date hereof, VSH shall revise, as appropriate, and implement policies and/or protocols to require the review within three business days of individuals' treatment plans for any individuals placed in seclusion or restraints more than three times in any four-week period, and modification of treatment plans, as appropriate.
- F. By 24 months from the Effective Date hereof, VSH shall develop and implement policies and/or protocols consistent with generally accepted professional standards of care governing the use of emergency involuntary psychotropic medication for psychiatric purposes, requiring that:
 - 1. such medications are used on a time-limited, short-term basis and not as a substitute for adequate treatment of the underlying cause of the individual's distress;
 - 2. a physician assess the patient within one hour of the administration of the emergency involuntary psychotropic medication; and
 - 3. in a clinically justifiable manner, the individual's core treatment team conducts a review (within three business days) whenever three administrations of emergency involuntary psychotropic medication occur within a four-week period, determines whether to modify the individual's treatment plan, and implements the revised plan, as appropriate.

G. By 18 months from the Effective Date hereof, VSH shall ensure that all staff whose responsibilities include the implementation or assessment of seclusion, restraints, or emergency involuntary psychotropic medications successfully complete competency-based training regarding implementation of all such policies and the use of less restrictive interventions.

X. PROTECTION FROM HARM

By six months from the Effective Date hereof, VSH shall provide the individuals it serves with a safe and humane environment, ensure that these individuals are protected from harm, and otherwise adhere to a commitment to not tolerate abuse or neglect of individuals, and require that staff investigate and report abuse or neglect of individuals in accordance with this Agreement and with Vermont state statutes governing abuse and neglect as found in 33 V.S.A. § 6901, et. seq. All staff persons who are mandatory reporters of abuse or neglect shall sign a statement that shall be kept with their personnel records evidencing their recognition of their reporting obligations. VSH shall not tolerate any mandatory reporter's failure to report abuse or neglect. Furthermore, before permitting a staff person to work directly with any individual, VSH shall investigate the criminal history and other relevant background factors of that staff person, whether full-time or part-time, temporary or permanent, or a person who volunteers on a regular basis. Facility staff shall directly supervise volunteers for whom an investigation has not been completed when they are working directly with individuals living at the facility. The facility shall ensure that nothing from that investigation indicates that the staff person or volunteer would pose a risk of harm to individuals at VSH.

XI. INCIDENT MANAGEMENT

By 12 months from the Effective Date hereof, VSH shall develop and implement, across all settings, an integrated incident management system that is consistent with generally accepted professional standards of care.

- A. By 12 months from the Effective Date hereof, VSH shall review, revise, as appropriate, and implement incident management policies, procedures and practices that are consistent with generally accepted professional standards of care. Such policies and/or protocols, procedures, and practices shall require:
 - 1. identification of the categories and definitions of incidents to be reported and investigated; immediate reporting by staff to supervisory personnel and VSH's executive director (or that official's designee) of serious incidents; and the prompt reporting by staff of all other unusual incidents, using standardized reporting across all settings;
 - 2. mechanisms to ensure that, when serious credible allegations of abuse, neglect, and/or serious injury occur, staff take immediate and appropriate

action to protect the individuals involved, including removing alleged perpetrators from direct contact with individuals pending the investigation's outcome;

- 3. adequate training for all staff on recognizing and reporting incidents;
- 4. notification of all staff when commencing employment and adequate training thereafter of their obligation to report incidents to VSH and State officials;
- 5. posting in each patient care unit a brief and easily understood statement of how to report incidents;
- 6. procedures for referring incidents, as appropriate, to law enforcement; and
- 7. mechanisms to ensure that any staff person, individual, family member, or visitor who, in good faith, reports an allegation of abuse or neglect is not subject to retaliatory action by VSH and/or the State, including but not limited to reprimands, discipline, harassment, threats, or censure, except for appropriate counseling, reprimands, or discipline because of an employee's failure to report an incident in an appropriate or timely manner.
- B. By 12 months from the Effective Date hereof, VSH shall review, revise, as appropriate, and implement policies and/or protocols to ensure the timely and thorough reporting of incidents to the Division of Licensing and Protection pursuant to 33 V.S.A. § 6901, et seq.
- C. By 12 months from the Effective Date hereof, whenever remedial or programmatic action is necessary to correct a reported incident or prevent reoccurrence, VSH shall implement such action promptly and thoroughly and track and document such actions and the corresponding outcomes.
- D. By 12 months from the Effective Date hereof, records of the results of every investigation of abuse, neglect, and serious injury shall be maintained in a manner that permits investigators and other appropriate personnel to easily access every investigation involving a particular staff member or individual.
- E. By 12 months from the Effective Date hereof, VSH shall have a system to allow the tracking and trending of incidents and results of actions taken. Trends shall be tracked by at least the following categories:
 - 1. type of incident;

- 2. staff involved and staff present;
- 3. individuals involved and witnesses identified;
- 4. location of incident;
- 5. date and time of incident:
- 6. cause(s) of incident; and
- 7. actions taken.

XII. QUALITY IMPROVEMENT

By 30 months from the Effective Date hereof, VSH shall develop, revise, as appropriate, and implement quality improvement mechanisms that provide for effective monitoring, reporting, and corrective action, where indicated, to include substantial compliance with this Agreement. The quality improvement methodologies shall be otherwise consistent with generally accepted professional quality improvement standards and shall:

- A. track data, with sufficient particularity for actionable indicators and targets identified in the Agreement, to identify trends and outcomes being achieved;
- B. analyze data regularly and, whenever appropriate, require the development and implementation of corrective action plans to address problems identified through the quality improvement process. Such plans shall identify:
 - 1. the action steps recommended to remedy and/or prevent the reoccurrence of problems;
 - 2. the anticipated outcome of each step; and
 - 3. the person(s) responsible and the time frame anticipated for each action step;
- C. provide that corrective action plans are implemented and achieve the outcomes identified in the Agreement by:
 - 1. disseminating corrective action plans to all persons responsible for their implementation;
 - 2. monitoring and documenting the outcomes achieved; and

- 3. modifying corrective action plans as necessary; and
- D. utilize, on an ongoing basis, appropriate performance improvement mechanisms to achieve VSH's quality/performance goals, including identified outcomes.

XIII. ENVIRONMENTAL CONDITIONS

By 12 months of the Effective Date hereof, VSH shall develop and implement a system to regularly review all units and areas of the hospital to which individuals being served have access to identify any potential environmental safety hazards and to develop and implement a plan to remedy any identified issues, consistent with generally accepted professional standards of care. The system shall attempt to identify potential suicide hazards and expediently correct them. Furthermore, VSH shall develop and implement policies and procedures consistent with generally accepted professional standards of care to provide for appropriate screening for contraband.

XIV. TERMS AND CONDITIONS

- A. The State represents that it will continually and periodically refine and revise the policies and/or protocols outlined in this Agreement to ensure compliance with the letter and intent of this Agreement. Upon request, the United States shall be provided with copies and an opportunity to provide
 - substantive comment upon any policies and/or protocols revised pursuant to this Agreement. The United States shall provide any such comments to the State no later than 30 business days following receipt of the draft policies or protocols.
- B. The State represents that it has educated, or will educate, all employees at VSH with respect to the policies and/or protocols outlined in this Agreement.
- C. The State shall maintain records to document its compliance with all terms and conditions of this Agreement. The State shall also maintain any and all records required by, or developed pursuant to, this Agreement.
- D. Until this matter is dismissed, the United States shall have unrestricted access to, and shall, upon request, receive copies of any documents, records, and information relating to the implementation of this Agreement, except where covered by attorney work product protections, attorney-client privilege, or under 26 V.S.A. § 1441-1443. VSH shall provide any requested documents, records, and information to the United States as soon as possible, but no later than within 20 business days of the request. The United States shall have reasonable access to all of VSH's buildings and facilities; staff and residents, including private interviews with staff with the consent of the State, and, where clinically appropriate, private

interviews with residents; and resident records, documentation, and information relating to the issues addressed in this Agreement except where covered by attorney work product protections, the attorney-client privilege, or under 26 V.S.A. § 1441-1443. VSH shall make all employees available so that they may choose to cooperate fully with the United States. The United States agrees to provide VSH with reasonable notice of any visit or inspection, although the United States and VSH agree that no notice shall be required in an emergency situation where the life, immediate health, or immediate safety of resident(s) is at issue. Nothing in this Agreement shall abridge the whistleblower rights of State employees or contractors under law.

- E. The United States may evaluate the appropriateness of an individual patient's placement as defined in this Agreement. The State agrees to fully cooperate with this process.
- F. The parties agree to the appointment of Dr. Mohamed El-Saabawi and Dr. Jeffrey Geller as the jointly-selected experts to monitor the State's implementation of this Agreement (the "Monitors"). The Monitors shall have full authority to independently assess, review, and report semi-annually on the State's implementation of and compliance with the provisions of this Agreement. The monitors may jointly or separately provide the State with technical assistance upon request. All reasonable costs and expenses of Dr. El-Saabawi shall be borne by the United States. All reasonable costs and expenses of Dr. Geller shall be borne by the State.
- G. The overall duties of the Monitors shall be to observe, review, report findings, and make recommendations to the parties with regard to the implementation of the Agreement. The Monitors shall regularly review the services provided to the residents at VSH to determine the State's implementation of, and compliance with, this Agreement. The Monitors shall give the State reasonable notice prior to all visits.
- H. Every six months, the Monitors shall provide the State and the United States with a single written report regarding the State's implementation efforts and its compliance with the terms of this Agreement. The State will take timely action to remedy any deficiencies cited in the report.
- I. If VSH closes and residents are moved to another facility or facilities, the United States reserves the right to evaluate the appropriateness of such placement. If the State contracts for any of the services to be delivered at VSH which are covered

under this Agreement, the Agreement shall be fully applicable to, and binding upon, any contracted services.

- J. If the United States maintains that the State has failed to carry out any requirement of this Agreement, the United States shall notify the State of any instance(s) in which it maintains that the State has failed to carry out the requirements of this Agreement.
- K. With the exception of conditions or practices that pose an immediate and serious threat to the life, health, or safety of VSH patient(s), the State shall take substantial steps within 90 days of notice of non-compliance. The State shall correct the claim of non-compliance within a reasonable time. During this period, the United States and the State shall coordinate and discuss areas of disagreement and attempt to resolve outstanding differences. If the United States and the State fail to reach an agreement, the United States is not limited in any fashion in pursuing its law enforcement obligations without further notice, including any adverse litigation against the State and/or seeking appropriate enforcement of any provision of this Agreement.
- L. The State shall notify the United States immediately upon the death of any resident and shall forward to the United States copies of any completed incident reports related to death, autopsies and/or death summaries of residents, as well as all final reports of investigations that involve residents' deaths.
- M. If, at any time, any party to this Agreement desires to modify it for any reason, that party will notify the other party in writing of the proposed modification and the reasons therefor. No modification will occur unless there is written agreement by the United States and the State.
- N. This Agreement will terminate four years after its Effective Date. If the parties agree that the State is in compliance with each of the provisions of this Agreement earlier than four years from the Effective Date of the Agreement, and have maintained compliance for at least one year, then the Agreement may terminate at an earlier date. The burden will be on the State and VSH officials to demonstrate such compliance.

Dated this	day of	, 2006

FOR THE UNITED STATES:

WAN J. KIM Assistant Attorney General Civil Rights Division

SHANETTA Y. CUTLAR Chief Special Litigation Section

JUDY PRESTON Deputy Chief Special Litigation Section

WILLIAM G. MADDOX LINDA L. KEYSER Lead Trial Attorneys U.S. Department of Justice Civil Rights Division Special Litigation Section 950 Pennsylvania Ave, NW Washington, DC 20530 (202) 514-6251 (202) 514-0212 (fax)

FOR THE STATE:

PAUL R. BLAKE
Deputy Commissioner for Health for Mental Health
Services
Vermont Department of Health
108 Cherry Street
P.O. Box 70
Burlington, VT 05402

WILLIAM H. SORRELL Attorney General By:

WENDY S. BEINNER, A.A.G. Chief Counsel Division of Mental Health Vermont Department of Health 1 Church Street P.O. Box 70 Burlington, VT 05402 (802) 657-4310